

REMARKS

Claims 1, 3-7, 9 and 11, as amended, are pending in this application. Claims 2 and 10 are canceled. Claim 8 is withdrawn without prejudice. Applicants reserve the right to file one or more continuation, divisional, or continuation-in-part applications directed to any withdrawn subject matter. Claim 1 is amended to recite that the animal is a dog or cat (basis claim 2, now canceled), that the level of omega-3 fatty acid is at least 2% (basis paragraph 0007 of specification) and that the omega-3 fatty acids are selected from DHA and EPA (basis, e.g., paragraph 0007 and 0011). No new matter is added. Applicants respectfully request entry of the amendments.

The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-7 and 9-11 are rejected as allegedly obvious under 35 U.S.C. § 103(a) over Reinhart, EP 0 687 257 A1 (Reinhart) in view of Reisbick *et al.*, Handbook of Essential Fatty Acid Biology: Biochemistry, Physiology, and Behavioral Neurobiology: Chapter 17 pp. 397-426 ("Reisbick"). Applicants respectfully traverse this rejection for at least the following reasons.

Applicants submit that one of ordinary skill in art after reading Reinhart would not have reasonably expected that the pet food product of Reinhart would have a positive effect on animal behavior, as Applicants have used that term in the claims. As the Examiner is aware, there must have been at the time of the invention a reasonable expectation of success. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-1208 (Fed. Cir. 1991), *cert. denied* 502 U.S. 856 (1991).

The pending claims encompass methods for influencing behavior in an animal, the methods comprising systemically administering to the animal in need thereof a diet comprising at least about 2% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids selected from the group consisting of eicosapentaenoic acid and docosahexaenoic acid as measured on a dry matter basis.

The office action states "[i]t would have been obvious to one of ordinary skill in the art that animals treated with the pet food product of Reinhart would influence the

behavior of the animals because Reinhart teaches that pet food product improved the general comfort and well-being of the animals.” (See office action at page 4).

One of skill in the art would however first need to identify the problem of improving the behavior of the dog or cat. Reinhart discloses nothing concerning behavior.

Reinhart actually discloses:

It will be appreciated that feeding pet animals with a diet consisting essentially of the pet food products as hereinbefore described not only reduces allergic and inflammatory conditions in the skin of the animals thereby improving the general comfort and well-being of the animals, but there is also a cosmetic effect in that the appearance of the skin of the animals is improved. In particular, by preventing and/or alleviating symptoms of skin diseases such as dermatitis and pruritis unsightly skin conditions can be avoided or diminished giving the animals an attractive, healthy appearance.

(See Reinhart at paragraph [0009]).

Thus, the phrase “improving the general comfort and well-being” disclosed in Reinhart is relative to an animal that is experiencing an allergic or inflammatory condition.

In contrast, the term “behavior” as recited by the claims includes:

[b]ehavior which can be altered for the positive by the systemic administration of omega-3 fatty acids include memory; learning; disorientation including at least one of awareness of surroundings, circling, aimless activity, inappropriate vocalization; interactions including at least one of family recognition, animal recognition, family interaction, animal interaction, greeting enthusiasm, attention seeking, response to verbal commands; activity such as agility and level of activity; irregular sleep pattern; housetraining; and any behavior associated with ARCD.

(See specification at paragraph [0009]).

Clearly, Reinhart could not teach or suggest methods of influencing behavior as recited by the instant claims based merely on Reinhart’s teaching of reducing allergic and inflammatory conditions. Indeed, there must have been at the time of the invention a

motivation to modify the teachings of the references cited. *Ecolochem, Inc. v. Southern California Edison Company*, 227 F.3d 1361, 1372 (Fed. Cir. 2000). Applicants respectfully submit that nothing in Reinhart teaches or suggests to one of ordinary skill in the art methods for influencing behavior in an animal as recited by the pending claims.

Applicants further submit that the claims recite the language “in need thereof.” The subject matter recited in the pending claims is not obvious, based upon the Reinhart reference alone or in combination with the Riesbick reference, because the Office has failed to show that there was an intent to use the compositions comprising at least about 2% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids as measured on a dry matter basis for influencing behavior in an animal. When a claim recites a method of treating a disorder to be performed on a patient ‘in need of’ such treatment, the proper construction of the claim is that the method be practiced in order to treat that specific disorder. *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1333-34, 68 U.S.P.Q.2d 1154, 1157-58 (Fed. Cir. 2003); *Rapoport v. Dement*, 254 F.3d 1053, 1060-61 (Fed. Cir. 2001). In *Rapoport v. Dement*, the claim under dispute recited:

A method of treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . .

254 F.3d at 1060. The court reasoned that the phrase “to a patient in need of such treatment” in the body of the claim would not have a proper antecedent basis without treating the claim preamble as claim feature. *Id.* at 1059. The court further explained that this claim feature required that the azapirone compound be administered in order to treat sleep apneas. *Id.* at 1060-61 (analyzing whether an allegedly anticipatory reference disclosed administration of an azapirone compound with intent to cure sleep apneas and stating that the reasons for administering the compound were relevant to an anticipation analysis). A subsequent Federal Circuit decision confirmed the conclusion of the *Rapoport* court. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (confirming that the *Rapoport*

method of treatment claim required that the method be practiced in order to treat sleep apneas). Thus, although the present rejection is an obviousness rejection and not an anticipation rejection, the claim must still be construed accordingly.

In *Jansen*, a similar method of treatment claim was interpreted to require that a drug combination be administered in order to treat the specified disorder. *Id.* In *Jansen*, the claim under dispute recited:

1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid.

Id. at 1330, 68 U.S.P.Q.2d at 1155. Relying in part on the *Rapoport* decision, the court interpreted the claim preamble as a statement of the “intentional purpose for which the method must be performed,” rather than “a statement of effect that may or may not be desired or appreciated,” thus rendering the preamble as an element of the claim. *Id.* at 1333, 68 U.S.P.Q.2d at 1158. That the specific type of anemia and the “in need” language was added to the claim during prosecution to achieve allowance of the claim bolstered the court’s conclusion that the two phrases should be read together and considered an element of the claim. *Id.* at 1334, 68 U.S.P.Q.2d at 1158. As stated by the court:

. . . that “need” must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances or their addition suggest they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megoblastic anemia is not practicing the claimed method, because *Jansen* limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. (emphasis added).

Id. at 1334, 68 U.S.P.Q.2d at 1158. Accordingly, a method claim further reciting “in need thereof” language should be properly construed such that the method is practiced with intent to reduce the particular disorder or symptom recited in the claim. Here, as in *Jansen*

and *Rapoport*, the pending claims recite that the methods are used on animals “in need thereof.”

Moreover, not all of the formulations of Reinhart meet the limitations of the claims as amended, thus selection of different formulations within the disclosure of Reinhart would be required. As Reinhart does not specifically focus on DHA/EPA levels, however, nor recognize their relevance in connection with behavior, there is nothing to motivate such optimization. As stated in MPEP 2144.05:

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)

There is nothing in Reinhart to suggest or motivate improving behavior by modifying the EPA/DHA levels.

The Examiner argues that this deficiency is met by Reisbick. Reisbick, however, is a general review article. It does not focus specifically on behavior of dogs or cats, nor does it address the deficiencies of Reinhart regarding selection of optimal formulations.

Reisbeck's conclusion is that

“Determining how omega-3 FA affect behavior will require experiments that differentiate possible mechanisms of action, including effects on membrane function or prostaglandin metabolism, either of which may be central or peripheral. We have presented one hypothesis – that a decrease in dopamine and/or dopamine receptors in the prefrontal cortex of deficient animals increases their receptivity to environmental stimuli. This hypothesis provides a possible alternative explanation for some of the previous results which have been interpreted as effects on learning.”

Reisbeck at p. 419-420. Fairly read, Reisbeck is an invitation to experiment. It would not provide a reasonable expectation of success in predicting that a particular diet would have a particular effect in a particular species. Moreover, it is the secondary reference. The Examiner has not provided any motivation why one of skill in the art starting with Reinhart would be motivated to pick up Reisbeck, without the motivation of hindsight provided by the instant application.

The Examiner has not identified any portion of the cited references that discloses or suggests the intent to practice the claimed methods for the purpose recited in the claims, or which provides motivation to optimize the formulations of Reinhart for that purpose. As the M.P.E.P. states, "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." (M.P.E.P. § 2141). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* The Office has failed to put forward a sufficient articulated reason as to why Applicants' claims are obvious in view of the cited references

For at least the foregoing reasons, Applicants respectfully submit that the rejection of claims 1, 3-7, 9 and 11 as obvious under 35 U.S.C. § 103 is improper and should be withdrawn.

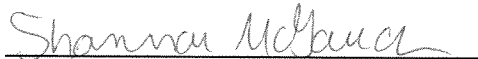
Conclusion

For at least the reasons discussed above, Applicants believe that pending claims are allowable. Further and favorable consideration is solicited. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

The Director is hereby authorized to charge any fees due, or credit any overpayments, to Deposit Account No. 50-2957.

Respectfully submitted,

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